K003087

NOV - 7 2000

C. INFORMATION REQUIRED BY THE SMDA OF 1990

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Sporicidin® Sterilizing and Disinfecting Solution (SSDS)

Sporicidin® International
121 Congressional Lane
Rockville, MD 20852

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Official Contact: Dr. Harold E. Plank
Technical Director

DATE SUMMARY PREPARED: October 27, 2000

Sporicidin® Sterilizing and Disinfecting Solution is a liquid chemical sterilant and high level disinfectant. These products have been assigned the product code Sterilant 80 MED by the FDA and designated as Class II medical devices.

1. DEVICE DESCRIPTION

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) is a liquid chemical sterilant and high level disinfectant. The product contains two solutions: a Buffer containing 2.02% phenol/phenate, and an activator containing 25% glutaraldehyde. When the two solutions are mixed, or activated, **SSDS** contains 1.12% glutaraldehyde and 1.93% phenol/phenate. The solutions are combined at the user level, resulting in the activated germicide.

SSDS is a liquid chemical sterilant and a high level disinfectant when used or reused according to the DIRECTIONS FOR USE included in the package insert. SSDS can be reused for a maximum of 14 days for high level disinfection and for sterilization or until Sporicidin Test Strips indicate that either the glutaraldehyde or phenol level falls below its MRC. The MRC for glutaraldehyde is 0.6%, and 1.3% for phenol/phenate.

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) must be used with Sporicidin Indicator Strips to verify that the MRC of active ingredients is present. It is recommended that SSDS be tested with Sporicidin Indicator Strips prior to each use.

2. **INTENDED USE OF DEVICE:**

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) is intended for sterilization or high level disinfection of medical and surgical instruments that require submersion.

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) should be used with medical devices that are not compatible with other sterilization or high level disinfection processes that can be biologically monitored.

SSDS can be reused for a maximum of 14 days for high level disinfection and for sterilization or until Sporicidin Indicator Strips indicate that either the glutaraldehyde or phenol level falls below its MRC.

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) should be used under the following contact conditions:

	Time	Temperature	MRC Levels	
			Glutaraldehyde	Phenol
Sterilization	12 hours	25 degrees C	0.6%	1.3%
High Level Disinfection	20 minutes	25 degrees C	0.6%	1.3%

3. **COMPARISON TO PREDICATE DEVICE (STATEMENT OF SUBSTANTIAL EQUIVALENCE)**

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) is substantially Equivalent to other liquid sterilants currently on the market including CIDEX® Activated Dialdehyde Solution. CIDEX® is 2.4% Glutaraldehyde solution while activated Sporicidin® Sterilizing and Disinfecting Solution contains as active ingredients 1.12% glutaraldehyde and 1.93% total phenol/phenate.

Both CIDEX® and Sporicidin® Sterilizing and Disinfecting Solution are similar in intended uses.

The safety and effectiveness of CIDEX and SSDS are comparable as they are sporicidal, virucidal, fungicidal, tuberculocidal, bactericidal and pseudomonacidal.

4. EFFICACY TESTING

All performance testing was conducted on formulations where the nominal concentration of glutaraldehyde was at levels less than in the current formulation (1.12%). The nominal level of phenol in all formulations tested was equivalent to that in the current formulation (1.93%).

MICROBIOLOGICAL TESTING showed SSDS to be sporicidal, tuberculocidal, virucidal, fungicidal, and bactericidal. Testing was conducted under worst case conditions with solution batches that were at the end of, or beyond, their two year expiration dates. SSDS was tested for sporicidal, bactericidal, fungicidal, tuberculocidal, and virucidal activity. The test battery included use-re-use manual stressing related to the product label directions for reuse. Results for SSDS are shown below:

Summary of Microbiological Test Data

Tests Performed	Results
SPORES Bacillus subtilis Clostridium sporogenes	Freshly activated and reused solution were effective at 12 hours at 25°C.
VEGETATIVE ORGANISMS Pseudomonas aeruginosa Salmonella cholerasuis Staphylococcus aureus	Freshly activated and reused solutions were effective within 10 minutes at 20°C.
Mycobacterium bovis Mycobacterium terrae	Freshly activated and reused solutions were effective within 20 minutes at 25°C.
FUNGI Trichophyton mentagrophytes	Freshly activated and reused solutions were effective within 10 minutes at 20°C.
NON-LIPID SMALL VIRUS Poliovirus Type II	Reused solutions were effective within 3 minutes at 23°C.
Coxsackie	Reused solutions were effective within 2 minutes at 23°C.
Rotavirus	Reused solutions were effective within 2 minutes at 20°C.
LIPID MEDIUM VIRUS Herpes simplex Type I Herpes simplex Type II	Reused solutions were effective within 3 minutes at 25°C.
HIV-1 (HTLV-III_{RF}) strain	Reused solutions were effective within 1 minute at 23°C.
Influenza Type A2	Reused solutions were effective within 10 minutes at 20-25°C.
LIPID LARGE VIRUS Vaccinia	Reused solutions were effective within 10 minutes at 20-25°C.
Cytomegalovirus	Reused solutions were effective within 2 minutes at 20°C.

SIMULATED IN-USE TESTING WITH ENDOSCOPES was also conducted. The test organism used was *Mycobacterium terrae*. Flexible fiber endoscopes made of a variety of material types were used. Solutions with active ingredient levels near or below the MRC were effective in reducing the level of *Mycobacterium terrae* by 10^6 on endoscopes in 15 minutes at 25° C. The testing demonstrated the effectiveness of SSDS as a high level Disinfectant under simulated use conditions.

CLINICAL (IN-USE) TESTING of used endoscopes further supports the efficacy of SSDS as a sterilant and high level disinfection under actual use conditions. Freshly prepared, unstressed, activated solution was used under labeled conditions for use as a high level disinfectant. Lower GI endoscopes used in patient care were immersed for 20 minutes at room temperature. Results of the study showed SSDS effectively disinfected endoscopes used in ptient care.

5. RESIDUE AND TOXICITY DATA

A residue test in which devices were soaked for 12 hours in a solution of SSDS (containing 0.5% glutaraldehyde and 1.64% phenol) demonstrated that no detectable glutaraldehyde was present in either rinse water or wipings of the external surface of the devices. SSDS treated devices do not raise safety concerns related to glutaraldehyde residues.

Phenol was present in the rinsings and wipings at less than 24 ppm, or 0.0024%. The phenol level is acceptable and does not represent a hazard to those treated with devices disinfected with SSDS according to the label directions. Phenol's demonstrated safety in other Sporicidin® International products at similar levels, as well as in mouth wash, supports that SSDS is safe for its intended use as a sterilant and high level disinfectant.

Glutaraldehyde is not detectable and phenol residues do not represent exposure greater than those which may result from use of other products with FDA clearance. Glutaraldehyde and phenol are well characterized chemicals. The toxicological and safety literature were reviewed.

6. MATERIAL COMPATIBILITY

Material compatibility testing demonstrated that SSDS can be used with a wide range of materials and endoscopes. SSDS is compatible with the materials and devices listed when used according to the instructions for use.

Plastics	Teflon Polyacetal Polysulfone Polyetherimide Polycarbonate Vinyl chloride Polybutylene terephthalate (PBT)
Synthetic Rubber	Silicone rubber Acrylonitrile-butadiens rubber (NBR) Neoprene Nitrile rubber Fluoro rubber
Glass	Optical Glass
Alumite	Anodized aluminum
Stainless Steel	
Adhesive	Epoxy adhesive
Sealing material	Silicone sealing compound

Refer to the reusable device labeling for additional material compatibility information.

7. STABILITY

SSDS has a shelf life of two years. Real time stability studies, together with accelerated aging and other testing, support a two year expiration date.

8. TEST STRIPS

Sporicidin Indicator Strips should be used prior to each use of SSDS. Sporicidin Indicator Strips indicate if the glutaraldehyde or phenol level falls below its MRC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2000

Mr. Harold E. Plank, D.D.S.
Technical Director
Sporicidin International
121 Congressional Lane
Rockville, Maryland 20852

Re: K003087
Trade Name: Modification To Sporicidin Sterilizing and Disinfecting Solution
Regulatory Class: II
Product Code: MED
Dated: September 27, 2000
Received: September 27, 2000

Dear Mr. Plank:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~K983194~~ K003087

Device Name: Sporicidin® Sterilizing and Disinfecting Solution (SSDS)

Intended Use:

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) is intended for sterilization of high level disinfection of medical and surgical instruments that require submersion. **SSDS is intended for reprocessing only heat-sensitive medical devices.**

Sporicidin® Sterilizing and Disinfecting Solution (SSDS) should be used under the following contact conditions:

	Time	Temperature
Sterilization	12 hours	25 degrees C
High Level Disinfection	20 minutes	25 degrees C

SSDS can be reused for a maximum of 14 days or until Sporicidin Test Strips indicate that either the glutaraldehyde or phenol level falls below its Minimum Recommended Concentration (MRC). The glutaraldehyde MRC is 0.6%; the phenol MRC is 1.3%.

Sporicidin Indicator Strips are intended for verifying the MRC of glutaraldehyde and phenol in SSDS during use. Sporicidin Indicator Strips should be used before each use of SSDS.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED0

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

Over-the-Counter Use ____
(Optional Format 1-2-96)

510(k) Number _____

(Division Sign-Off)
Division of Dental, Infection Control
and General Hospital Devices

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003087